

**SAFETY DATA SHEET**

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 Date: 01/17/2019

Generic Name: Fluoxetine Tablets, 60mg USP

Brand Equivalent: Prozac<sup>®</sup>  
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<b>SECTION 1: IDENTIFICATION</b>	
<b>Product Name</b>	Fluoxetine Tablets, USP 60mg
<b>Active substance</b>	Fluoxetine Hydrochloride
<b>Synonyms</b>	N/A
<b>Formula</b>	C <sub>17</sub> H <sub>18</sub> F <sub>3</sub> NO. HCl
<b>Therapeutic Class:</b>	Selective Serotonin Reuptake Inhibitor
<b>Chemical Name</b>	(±)-N-methyl-3-phenyl-3-[(α,α,α-trifluoro-p-tolyl)oxy]propylamine hydrochloride
<b>Chemical Class</b>	Phenylpropylamine
<b>How Supplied</b>	60mg -Tablets white to off white, Capsule shape film coated tablet with scored line on both sides debossed with "SG 422" on one side and plain on other side.
<b>Manufacturer Name &amp; Address</b>	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
<b>Telephone No.</b>	631-434-2723

## 2. HAZARDS IDENTIFICATION:

**GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION:** According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

**EU LABELING/CLASSIFICATION:** According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC. **EMERGENCY OVERVIEW: Product Description:** This product consists of a hard gelatin capsules in color combinations noted in Section 1 or blue oval tablets. **Health Hazards:** In the workplace, exposure from dusts of capsules or tablets has the potential for irritation of contaminated skin or eyes. Non-therapeutic ingestion may be harmful. May cause adverse central nervous system effects. Chronic ingestion may cause serious or fatal systemic toxicity. Ingestion may cause allergic reactions. In therapeutic use, the most common adverse effects have been headache, difficulty concentrating, memory impairment, confusion, weakness, and unsteadiness. As a selective serotonin reuptake inhibitor, this material may cause harm to the fetus. These effects may be possible as a result of workplace exposure. See Section 11 (Toxicological Information) for more information on possible therapeutic use effects. **Flammability Hazards:** This product is combustible and can ignite if highly heated or if exposed to direct flame. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides). **Reactivity Hazards:** This product is not reactive. **Environmental Hazards:** May cause harm to aquatic organisms if accidentally released. All environmental release should be avoided. **Emergency Recommendations:** Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

<b>3. Composition/Information on ingredients</b>		
<b>Components</b>	<b>CAS-No</b>	<b>Concentration (%w/w)</b>
Fluoxetine Hydrochloride	56296-78-7	8.94
Mannitol, USP (Pearlitol 50C )	69-65-8	*
Microcrystalline Cellulose, NF	9004-34-6	*
Corn Starch, NF (400L-Modified Food Starch)	9005-25-8	*
Povidone USP (Plasdone K- 29/32)	9003-39-8	*
Magnesium Stearate, NF	557-04-0	*
Sheffcoat white 04	112926-00-8	*

\* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

<b>4. FIRST AID MEASURES</b>	
<b>Eye contact</b>	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention immediately.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
<b>Inhalation</b>	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
<b>Ingestion</b>	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Causes eye burns. May cause drowsiness or dizziness. Increased heart rate. Seizures. May cause damage to the liver.
<b>Indication of immediate medical attention and special treatment needed</b>	Fluoxetine Hydrochloride - Cardiac and vital signs monitoring is recommended, along with general symptomatic and supportive measures. No specific antidote is known. Forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit. In limited human overdose experience, seizures have been reported. Appropriate seizure precautions are advised for any patient regularly taking fluoxetine who has been exposed to an acute overdose. Based on experience in animals, which may not be relevant to humans, fluoxetine-induced seizures that fail to remit spontaneously may respond to diazepam.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

### **5. FIRE-FIGHTING MEASURES**

<b>Suitable extinguishing media</b>	Water. Carbon dioxide (CO <sub>2</sub> ). Dry chemical.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Hazardous decomposition products formed under fire conditions.
<b>Special protective equipment and precautions for firefighters</b>	Wear self-contained breathing apparatus and protective clothing.

<b>6. ACCIDENTAL RELEASE MEASURES</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	Wear suitable protective clothing, gloves and eye/face protection. Do not breathe dust. See Section 8 of the SDS for Personal Protective Equipment.
<b>Methods and materials for containment and cleaning up</b>	The following are recommended for manufacturing or other situations where exposure to contents may occur. Do not sweep. Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping.

<b>7. HANDLING AND STORAGE</b>	
<b>Precautions for safe handling</b>	All employees who handle this material should be thoroughly trained to handle it safely. Do not eat or drink while handling this material. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection).
<b>Conditions for safe storage, including any incompatibilities</b>	Containers of this material must be properly labeled. Recommended Storage Temperature: 20-25°C (68-77°F). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.
<b>Specific End Use</b>	This is a human pharmaceutical
<b>Protective Practices During Maintenance Of Contaminated Equipment</b>	When cleaning non-disposable equipment, wear appropriate personal protective equipment.

<b>8. Exposure controls/Personal protection</b>	
<b>Exposure Limits/Control Parameters: Ventillation And Engineering Controls</b>	Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used.
<b>Workplace Exposure Limits/Control Parameters</b>	There are no occupational exposure limits for this product.
<b>Respiratory Protection</b>	None needed for normal handling of this product. For large spill response or tasks involving generation of aerosols, use the appropriate Self-Contained Breathing Apparatus (SCBA) pressure-demand or other positive-pressure mode.
<b>Eye/face protection</b>	Wear splash goggles or safety glasses as appropriate for the task.
<b>Skin protection</b>	Use appropriate protective clothing for the task (e.g., lab coat, etc.).
<b>Hand protection</b>	Wear nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response.

<b>9. PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>General Information</b>	
<i>Appearance</i> <b>Physical State</b> <b>Color</b>	White to off white capsule shape Tablets As described in Section 1.
<i>Odour</i> <b>Odour</b> <b>Odor Threshold</b>	Practically odorless Not applicable.
<b>pH</b>	Not available
<i>Other information</i> <b>Bulk density</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Melting point/freezing point</b>	159°C (318.2°F) Fluoxetine Hydrochloride
<b>BOILING POINT @ 760 mmHg</b>	395.1°C (743.2°F) Fluoxetine Hydrochloride
<b>Flash point</b>	Not applicable
<b>Flammability limit – lower (%)</b>	Not available.
<b>Flammability limit – upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available
<b>Explosive limit - upper (%)</b>	Not available
<b>Vapor pressure</b>	Not available
<b>Vapor density</b>	No data available.
<b>Relative Density</b>	Not available
<b>Solubility (water)</b>	Soluble in water @ 25°C: 14 mg/mL Fluoxetine Hydrochloride
<b>Partition coefficient (n-octanol/water)</b>	0.930 (pH 5) Fluoxetine Hydrochloride 1.780 (pH 7) Fluoxetine Hydrochloride 2.630 (pH 9) Fluoxetine Hydrochloride
<b>Auto-ignition temperature</b>	Not available
<b>Decomposition temperature</b>	Not available
<b>Viscosity</b>	Not available
<b>Other information</b> <b>Explosive properties</b>	Not explosive
<b>Oxidizing properties</b>	The substance or mixture is not classified as oxidizing.

<b>10. Stability and Reactivity</b>	
<b>Reactivity</b>	Not water reactive
<b>Chemical Stability</b>	Stable under normal conditions
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	None known.
<b>Hazardous Decomposition products</b>	Hazardous decomposition products formed under fire conditions.
<b>Incompatible materials</b>	Strong oxidizing agents.

<b>11. Toxicological Information</b>	
<b>Symptoms Of Exposure By Route Of Exposure</b>	The main expected routes of occupational exposure to this product are via inhalation of dusts, eye and skin contact. Exposure may cause allergic reaction. Exposure may also cause effects described under 'Other Potential Health Effects'.
<b>Inhalation</b>	Dusts may irritate the nose and upper respiratory system. Symptoms may include sneezing, coughing, and nasal congestion.
<b>Contact With Skin or Eyes</b>	Mild irritation possible. Symptoms may include itching and redness and swelling
<b>Skin Absorbtion</b>	No information available.
<b>Ingestion</b>	May be harmful or toxic. May irritate the mouth, throat, and gastrointestinal system
<b>Injection</b>	Not a likely route of exposure.
<b>Aspiration hazard</b>	No aspiration toxicity classification
<b>Carcinogenicity</b>	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
<b>Reproductive Toxicity</b>	Due to lack of data the classification is not possible
<b>Developmental Toxicity</b>	Due to lack of data the classification is not possible
<b>Pharmacokinetics/Toxicokinetics</b>	Due to lack of data the classification is not possible
<b>Other Toxicity Information</b>	Due to lack of data the classification is not possible

<b>12. Ecological Information</b>	
<b>Ecotoxicity</b>	This product may be harmful or fatal to contaminated plant and animal-life (especially if large quantities are released). This product has not been tested for aquatic toxicity.
<b>Persistence and degradability</b>	This product has not been tested for persistence and biodegradability. No predicted values are available.
<b>Bioaccumulative potential</b>	This product has not been tested for bio-accumulation potential.
<b>Mobility in soil</b>	This product has not been tested for mobility in soils.
<b>Other adverse effects</b>	The components of this product are not listed as having ozone depletion potential.

<b>13. Disposal considerations</b>	
<b>Disposal instructions</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Precautions to be followed during waste handling</b>	Wear proper protective equipment when handling waste materials



<b>14. Transport Information</b>	
<b>U.S. Department of Transportation</b>	This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101
<b>Transport Canada Transportation of Dangerous Goods Regulations</b>	This material does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada
<b>International Air Transport Association (IATA):</b>	This product does not meet the criteria as Dangerous Goods, per rules of IATA
<b>International Maritime Organization Designation (IMO)</b>	This product is NOT classified as Dangerous Goods by the International Maritime Organization.
<b>European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)</b>	Does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.
<b>Transport in Bulk according to the IBC CODE</b>	Not applicable.
<b>Environmental hazards</b>	This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and no component is not specifically listed in Annex III under MARPOL 73/78

<b>15. Regulatory Information</b>	
<b>U.S. Sara Reporting Requirements</b>	The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
<b>U.S. SARA Threshold Planning Quantity</b>	There are no specific Threshold Planning Quantities for components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.
<b>U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21):</b>	ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No
<b>U.S. CERCLA Reportable Quantity (RQ):</b>	Not applicable.
<b>U.S. TSCA Inventory status</b>	This product is regulated under Food and Drug Administration standards; this product is not subject to requirements under TSCA.
<b>OTHER U.S. Federal Regulations</b>	Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.
<b>California Safe Drinking water and Toxic Enforcement Act (PROPOSITION 65)</b>	No component of this product is listed on the California Proposition 65 Lists

<b>16. Other information</b>	
<b>Recommended Restrictions for Use:</b>	Not available
<b>Prepared on</b>	01/17/2019
<b>Revision</b>	00
<b>Disclaimer</b>	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.